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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,909	04/04/2001	David L. Thompson	P-8999	3722

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MEDTRONIC, INC.
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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

15

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,909

Applicant(s)

THOMPSON ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/28/04 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The Applicant amended independent claim 1 to overcome the rejection of record, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 112

2. Claims 1-5 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically:

- In claims 1 and 24, the Applicant claims sensor(s) are attached to “a peripheral limb”, but the Examiner finds in the specification the sensor(s) are attached to the wrist (specification – page 4, lines 21-23) and not a peripheral limb which could also include the foot.
- In claim 1, the Applicant claims “continuously collected physiological data”, but the Examiner finds in the specification the data is continuously transmitted (specification – page 5, lines 5-7), but can find in the specification that the data is continuously collected.
- In claim 21, a vibratory sensor is claimed, but the Examiner is unable to find a vibratory sensor disclosed in the specification.

New matter may not be introduced into the application at this point in the prosecution process.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. Claim 1, 2, 4, 5, 14, 15 and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tockman et al. (US 5540727) in view of Tavori (US 5724025). Tockman et al. teach a method and apparatus to automatically optimized the pacing mode and pacing cycle parameters of an implantable stimulating device (read as pacemaker or defibrillator) using and optimization sequence, read as providing a dynamic closed loop self monitoring system. The apparatus comprises a pacemaker (10), a micro-controller (32) an RF telemetry link (40), and external sensors/ monitors (42-50), including and oximeter (50). (figure 1; col. 1 @ 8-15; col. 1 @ 66 – col. 2 @ 15; col. 3 @ 58-62; col. 3 @ 66 – col. 4 @ 24; col. 5 @ 8 – col. 6 @ 59).

The monitor (42) and sensor (44, 46, 48, 50, 52) are read to be the external sensor. It is well established that it is not novel to make two elements integral (Howard v. Detroit Stove Works, 150 US. 164 (1893)).

As to an external sensor module transmitting physiological data by way of the sensor signals to the IMD using the telemetry link (RF signals) so the processor in the IMD can process the data collected by the external sensor to implement dynamic closed loop self monitoring therapy delivery, the processing of the sensor data can be performed by the external monitor (42) or by the microprocessor (32) of the implanted device (10) (col. 4 @ 52-56). As shown in figure 2, the sensor data enters the “software” of the implanted device microprocessor (32) at (figure 2 - 56) and follows path (figure 2 - 66) to the input block (figure 2 - 68) (col. 5 @ 44-49). The sensor data is transferred to the “software” located in the microprocessor (32) of the implanted device (10) using telemetry/ RF signals (40) (figure 1). The implementation of the “software” of figure 2 is read as implementing dynamic closed loop self monitoring therapy

delivery, hence the rejection of record stands. It is emphasized the microprocessor of the internal device can process the physiological data, hence teaching the IMD processor processes the physiological data to produce therapy delivery control signals in implementation of dynamic, closed loop self-monitoring therapy delivery.

As to continuously transmitting the continuously collected data, Tockman et al. teach providing the necessary sensing and monitoring structure to iteratively alter pacing parameters (col. 2, lines 1-4), the necessary structure read to be the capability to continuously monitor and continuously transmit the data.

As discussed in the previous four paragraphs of this action, Tockman et al. disclose the claimed invention except for the sensors coupled to the surface of the limb of the patient by an adhesive material, the system comprising a housing containing a switching means.

Tavori teaches physiological monitoring using the sensors coupled to the surface of the limb of the patient by an adhesive material, the system comprising a housing containing a switching means for the purpose of conveniently mounting the sensors to collect physiological data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the sensors coupled to the surface of the limb of the patient by an adhesive material, the system comprising a housing containing a switching means in the Tockman et al. system in order to enable easy accurate monitoring of the physiological parameters so the patient's condition is accurately reflected, appropriate medical decisions can be made, and the patient receives treatment that meets his needs (abstract; figure 1; col. 1 @ 12-25; col. 2 @ 46-56; col. 4 @ 38 – col.5 @ 17).

4. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tockman et al. (US 5540727) in view of Tavori (US 5724025 and further in view of Kopotic (US 6470199). As discussed in paragraph 3 of this action, Tockman et al. disclose the claimed invention except for providing an external sensor module in the configuration of a sock.

Kopotic et al. teach oximetry sensing using an oximeter sensor module in the configuration of a sock for the purpose of securing the oximeter in place. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a oximeter sensor module in the configuration of a sock in the Tockman et al. system in order to properly position the sensor on the patient, avoiding misalignment of the emitter and detector of the oximeter leading to faulty oximeter readings, inaccurate determination of the pulse rate and blood oxygen saturation and inappropriate therapy (col. 1 @ 19-24 and 34-52; col. 2 @ 30-42; col. 12 @ 55-56).

The Applicant's argument files 1/28/04 have been fully considered but they are not convincing. The Applicant argues the Examiner has not provided proper motivation to combine the reference, hence a prima facie case of obviousness has not been established. The Examiner disagrees. The motivation to combine the references was cited from Kopotic et al., as noted in the rejection above and as repeated here, the rejection being: in order to properly position the sensor on the patient, avoiding misalignment of the emitter and detector of the oximeter leading to faulty oximeter readings, inaccurate determination of the pulse rate and blood oxygen saturation and inappropriate therapy (col. 1 @ 19-24 and 34-52; col. 2 @ 30-42; col. 12 @ 55-56).

Specification

5. The amendment filed 1/28/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in claims 1 and 24, “a peripheral limb”, in claim 1, the Applicant claims “continuously collected physiological data”, and in claim 21, a vibratory sensor. Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

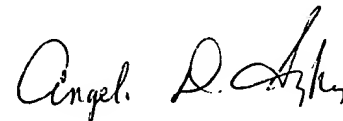
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FRP
4/4/04



**ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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